

subject matter.

To provide a complete response, applicants elect claims 1-14, 43-48, 63-68, 81, 83-91, 92-101, 102, 104 and 106-116 of Group I for examination purposes in the subject application. According to the communication, the Group I claims are drawn to a method of repairing genitourinary tract tissue, in which the dysfunction is urinary stress incontinence related to sphincter defects.

This election is made with traverse, as all of the claims are classified in class 514, subclass 44, due to the common categorization of their subject matter in terms of repairing a genitourinary tissue defect or dysfunction, a musculoskeletal tissue defect or dysfunction, or a bone defect or dysfunction utilizing a muscle-derived cell population according to applicants' invention.

In particular, the claims of Groups I-III are directed to methods of repairing genitourinary tract tissue, wherein the dysfunction or defect of the genitourinary tract tissue relates to the sphincter, the urethra, or the bladder, all of which are muscle-related tissues/organs that can be repaired using a treatment comprising muscle-derived cells described by applicants.

It is believed that the claims of Groups I-III should properly be designated as being drawn to a method of repairing a genitourinary tract tissue defect or dysfunction related to sphincter defects (Group I), urethral defects (Group II) or bladder dysfunction/defects (Group III), and should not be drawn specifically to urinary stress incontinence as the dysfunction of the genitourinary tract tissue. This is because

genitourinary tract dysfunctions treatable by the claimed methods include dysfunctions other than urinary stress incontinence, which is considered to be a dysfunction associated with the sphincter, the urethra and/or the bladder.

Indeed, both bladder dysfunction and urinary stress incontinence are genitourinary tract dysfunctions that can be treated by the claimed method comprising, for example, introducing muscle-derived cells as described by the applicants into bladder wall tissue to modulate muscle contractility in the bladder wall. In Groups I, II and III, the Examiner has unduly limited the subject matter to urinary stress incontinence as the only genitourinary tract tissue dysfunction related to sphincter defects, urethra defects, or bladder dysfunction, respectively. In reality, sphincter defects (and urethral defects and bladder dysfunctions) are associated with genitourinary tract tissue dysfunctions other than just urinary stress incontinence.

It is therefore suggested by the applicants that the subject matter of claim Groups I-III (and also Group IV) should be considered as being drawn to repairing genitourinary tract tissue defects or dysfunctions, without limitation to a specific defect or dysfunction, since numerous conditions of the genitourinary tract, e.g., urinary stress incontinence, sphincter defects, urethra defects, bladder defects and erectile dysfunction, are reparable by practice of the present methods.

It is also believed that, for search purposes, the art is sufficiently related among the subject matter of the groups to allow for a search of the art which covers a combination of Groups I-III, or Groups I-IV, as one group. Such a search would be able

to be conducted without undue burden on the Examiner. In this regard, it is kindly requested that if the Examiner finds in his search that the subclass(es) of art are close or pertain to more than one group of claimed subject matter, then the Examiner will search the relevant claims as a combined group, rather than as separate groups. In this way, the total number of groups requiring a separate search and examination will be reduced.

In sum, it is respectfully believed that that one search can be carried out on the subject matter of all of the groups, and especially on the combined subject matter of Groups I-III, or Groups I-IV, without a serious or heavy burden being imposed on the Examiner in conducting the search. Additionally, it is respectfully requested that the subject matter of claim Groups I-III (and also Group IV) should be considered as being drawn simply to repairing genitourinary tract tissue defects or dysfunctions, without limitation to a specific defect or dysfunction, such as urinary stress incontinence. A combination of Groups I-III, or Groups I-IV, is believed to be searchable without a serious burden or imposition on the Examiner's task and time.

Further, in view of the scope of applicants' claim 1 covering a method of repairing injured genitourinary tract tissue, applicants submit that it is inappropriate for the Patent Office to adopt a mode of patenting which ultimately serves to deny to applicants the ability to protect the full generic scope of the claimed subject matter. For this reason, applicants respectfully request reconsideration of the requirement to unduly limit a claim such as claim 1 to a particular dysfunction or defect of the genitourinary

tract (i.e., urinary stress incontinence) as set forth in the instant communication under 35 U.S.C. §121.

Finally, it is respectfully submitted that the inclusion of claims 76-80, directed to a method of isolating and purifying muscle derived stem cells, among the claims of Group V appears not to be in keeping with the content and classification of the subject matter of the Group V claims, which, according to the Examiner, relates to a method of repairing musculoskeletal tissue. The subject matter of claims 76-80 does not relate to a method of repairing musculoskeletal tissue, but rather describes a method of obtaining muscle-derived stem cells that are suitable for use in all of the claimed methods. Thus, reconsideration of claims 76-80 as part of the Group V claims is believed to be warranted.

AUTHORIZATION

Should fee(s) additional to those paid herein be deemed necessary for the filing of this response, the Commissioner is hereby authorized to charge any fee(s) which may be deemed assessable in this application to Deposit Account No. 13-4500, Order No. 2710-4007US1.

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